

**PATENT**/Docket No. PC9953D

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Response to 01/18/05 Office Action

**Remarks/Arguments****Restriction Requirement**

The 1/18/2005 Office Action (OA) presented 6 Groups from which Applicant was to elect an invention. Applicant elects Group II. Amendments to the claims have been completed to bring the claims within the scope of Group II. If unelected subject matter was inadvertently not removed by said amendments, Applicant invites Examiner to contact the below-signed attorney to discuss inadvertent inclusion of non-elected subject matter.

Claims 3 and 6 are canceled because they are drawn to non-elected subject matter.

Applicant reserved at the time of the preliminary amendment, and continues to reserve, the right to file on non-elected subject matter canceled during the prosecution of this pending matter.

**Priority & Title**

Applicant has corrected the priority claim reference by providing the patent number of the then co-pending application which issued as US 6,602,874. Applicant has also corrected the title as requested in the 1/18/2005 OA as requested by adding "PiperidinyI" to the title. Applicant requests withdrawal of these concerns.

**Claim Objections**

Claims 9, 12, and 13 were objected to for being duplicate of claim 8. Applicant disagrees, but in an effort to facilitate prosecution, claims 9, 12, and 13 were canceled, reserving the right to traverse the objection in any subsequently filed application concerning said subject matter. Applicant respectfully requests withdrawal of this objection.

Claims 14 and 15 were objected to as being duplicate of claims 10 and 11, respectively. Applicant disagrees, but in an effort to facilitate prosecution, claims 14 and 15 were canceled, reserving the right to traverse the objection in any subsequently filed application concerning said subject matter. Applicant respectfully requests withdrawal of this objection.

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**Claim Rejections**

Claims 9, 11, 13, and 15 were rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claims have been canceled for other reasons, reserving the right to file claims to the canceled subject matter in any subsequently filed application. Applicant respectfully requests withdrawal of this rejection.

Claims 8-15 were rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 9 and 12-15 have been canceled for other reasons, reserving the right to file claims to the canceled subject matter in any subsequently filed application. The 1/18/2005 OA takes exception with the words "preventing" and "prevention", stating that the invention is not enabled for preventing any diseases. Applicant disagrees, but in an effort to facilitate prosecution, will remove said words from the remaining claims, reserving the right to traverse the rejection in any subsequently filed application concerning said subject matter. Applicant has amended claims 8 and 10. Applicant respectfully requests withdrawal of this rejection.

Claims 8-15 were rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 9 and 12-15 have been canceled for other reasons, reserving the right to file claims to the canceled subject matter in any subsequently filed application. The 1/18/2005 OA states that while being enabled for treating generalized anxiety disorders and migraine, the specification does not reasonably provide enablement for treating the other listed diseases or treating every "disorder or condition that can be treated or prevented by enhancing serotonergic neurotransmission". Applicant traverses with regard to claims 8 and 10 because said language does not occur in said claims. Applicant disagrees with the rejection with regard to claim 11 also, but in an effort to facilitate prosecution, will cancel claim 11, reserving the right to traverse the rejection in any subsequently filed application. The 01/18/2005 OA also took exception with the lists of diseases, stating that the claims were enabled for only anxiety disorders and migraine.

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Applicant disagrees with the rejection with regard to claims 8 and 10, but in an effort to facilitate prosecution, will cancel the rejected subject matter, reserving the right to file claims to the canceled subject matter in any subsequently filed application. Applicant respectfully requests withdrawal of this rejection.

Claims 1-6 and 8-15 were rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The 01/18/2005 OA states that the specification is not adequately enabled for the scope of fused rings that have piperidine rings as radical R<sup>1</sup>. Applicant traverses.

The test for enablement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm) 1983), *Aff'd. sub. nom.*, *Massachusetts Institute of Technology v. A.Z.B. Fortia*, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985). Nothing more than objective enablement is required, and therefore, it is irrelevant whether the teaching is provided through broad terminology or illustrative examples. *In re Wright*, 000 F.2d 1557, 1561 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). In *In re Brana*, 51 F3d 1560 34 USPQ2d 1436 at 1441 (1995), the court stated:

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

*In re Marzocchi*, 58 C.C.P.A. 1069, 439 F.2d 220, 223, 169 U.S.P.Q. (BNA) 367, 369 (CCPA 1971). From this it follows that the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. *Id.* at 224, 169 U.S.P.Q. (BNA) at 370. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility

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does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. See *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. (BNA) 48, 51 (CCPA 1981). [Emphasis in original. Footnote omitted.]

Applicant is not required to provide clinical data as if applying to the FDA for approval of a drug candidate; by providing the assays and how to make the compounds of the claimed invention, Applicant believes that the enablement requirement has been satisfied:

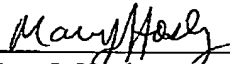
Usefulness in patent law, and in particular in context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were [the court] to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer. [*Brana*, at 1442-1443.]

Applicant respectfully requests withdrawal of this rejection.

### Conclusion

Applicant believes that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact the below-signed attorney. An extension is needed; Applicant requests any such extension and authorizes the Commissioner to charge Deposit Account 16-1445, and to credit any overpayments.

Respectfully submitted,

  
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